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The authors (or their relations) have no conflict of interest to declare

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Title Page

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Manuscript Type: Research

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Abstract

Objectives: The main aim of the review is to identify potentially effective distraction techniques for the 4 to 10 age range whilst reducing the need for sedation. Objectives also included assessment of the applicability of distraction for the 4-10 age range and, where appropriate to identify potential cost implications and assess the interventions' impact on image quality.

Key Findings: *A priori* search terms, inclusion and exclusion criteria were developed and two independent reviewers were employed to assess study quality. Five studies fitted the criteria of the systematic search strategy. The studies implemented a range of distraction and preparatory techniques resulting in paediatric patients being able to complete an MRI scan to a diagnostic level in the 4 to 10-year-old age category with a sedation rate of 5-20%. All interventions included in the review required time with the patient prior to the scan.

Conclusion: There are a range of efficacious techniques that can be employed to reduce the sedation rates in children aged 4-10 years, whilst allowing diagnostic images to be acquired. The introduction of play and the engagement with the patient prior to the scan appear to be indicators of intervention effectiveness. The efficacy of these interventions does not appear to be linked with proprietary equipment.

Implications for Practice: Age appropriate interventions are necessary for children of different ages and these distraction interventions may be implemented within departments for little cost with notable benefits in terms of sedation.

Highlights

- This article focuses on the 4-10 age range for patients undergoing MRI
- There are a number of different ways that patients can be prepared before MRI scans, most effect appears to be play and simulation.
- Sedation and general anaesthesia rates can be reduced to approx. 20% with these methods.
- These are not necessarily dependent on expensive pieces of equipment but the nature of the intervention.

Key Words

Distraction techniques; MRI; Paediatrics

Introduction

The Platt Report was produced at the request of the Ministry of Health in the United Kingdom covering the need for play for children undergoing treatment in hospitals.[1] It led to the establishment of the National Association for the Welfare of Children in Hospital (NAWCH) in 1961 which campaigned for child and family-centred care.[2] Despite these changes, a public enquiry into children's heart surgery at Bristol Royal Infirmary found evidence that children were still being treated as small adults and their needs were identified in relation to different size of facilities (e.g. smaller beds).[3] Whilst the Labour government developed the National Service Frameworks[4] Mathers et al[5] examined the extent to which these were being adhered to across the country and found that services for children were provided in 84% of adult hospitals. More recently guidance from the College of Radiographers[6] has provided further guidance on improving the services, research appears to point towards a disparity in experience between paediatric specific services and those provided in the majority of hospitals.[5]

Paediatric patients are particularly sensitive to the harmful effects of ionising radiation. Computed Tomography's (CT) use of ionising radiation can be viewed as a public health concern.[5,6] Magnetic resonance imaging (MRI) can be seen as the modality of choice for neurology, musculoskeletal and cardiovascular investigations in paediatric patients.[7] MRI can however, prove difficult for paediatric patients due to the need to remain immobile for, potentially, a long period of time. This is often in an enclosed space, with loud machinery, and in an unfamiliar environment.[8] The confined space of the MRI and the long period of time for the scan to take place, can increase the anxiety of children in particular during these procedures. This anxiety can reduce the compliance of children, resulting in increased general gross movement and reduced compliance throughout the procedure.[9] In addition, the increased anxiety can have physiological effects; increased respiratory rate, peristalsis and fluid flow can further impact image quality.[10]

Consciousness-altering drugs (e.g. anxiolytics) and general anaesthetic (GA) have been used to ensure patient compliance and produce diagnostic results[11] often with mixed results.[12,13] To mitigate the potential harm associated with pharmacological agents in paediatric patients (e.g. iatrogenic effects of drugs used to anaesthetise and sedate patients[14]) distraction techniques can be seen as an alternative to sedation.[15]

Munn and Jordan[16] have provided guidance suggesting that healthcare professionals may consider using some of the strategies highlighted within their systematic review. However, it has been noted that there is a non-uniformity of ages assessed.[16] This is an issue, as between the ages of 0-18, children develop at varying rates.[14] Therefore this current literature review has chosen to focus on a set age range (4-10 years). This age range is based on the ability of children to understand the concept of illness, be accepting of age appropriate information and, the top end of the age range (i.e. 10 years old), can be seen as the time when children will reach the maximum weight (i.e. 30 kg) that sedation will be applied at.[13,14]

Throughout this paper the term sedation will be used for a chemical-induced reduction in consciousness including the application of GA, anxiolytic and hypnotic drugs to aid in patient compliance. This is because, the overall aim should be to reduce the use of all sedative/GA strategies in paediatric examinations, given the potential impact on the patient if mismanaged.[14]

Primary Objectives

- Identify effective approaches to implementing distraction techniques in MRI that enable children age 4-10 years to avoid sedation.
- Assess the applicability of distraction approaches for the 4-10 age range.

Secondary Objectives

- Identify potential cost implications of implementing distraction techniques/services
- Identify potential distraction approaches that maintain image quality.

Method

A systematic search was employed to identify appropriate literature. Preliminary searches revealed that the interventions used to distract paediatric patients were too heterogeneous to provide an effective meta-analysis. *A priori* inclusion and exclusion criteria were developed prior to the search being conducted and this is seen in table 1. All types of interventions were included in the criteria so that a thorough assessment across types could be made. As a minimum, the output measure of comparison between sedation and distraction intervention is required. The outcome measures of cost and image quality were extracted where available.

Search strategy and article selection

A comprehensive search was completed using the terms and combinations detailed in Table 2 using a PICO (Population, Intervention, Comparison, Outcome) methodology.[17] Allied and Complementary Medicine database (AMED), Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medical Literature Analysis and Retrieval System Online (MEDLINE), ScienceDirect, PsychArticles, PsychInfo, Psychology and Behavioural Science Collection databases from 2011 (date of previous systematic review) until November 2018 were searched. A search of the references of the final five articles was also completed. An overview of the process can be seen in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) chart (fig. 1).

Steps taken to reduce bias

Two independent reviewers issued quality ratings using an adapted Caldwell et al[18] framework with criteria adapted from Bettany-Saltikov and McSherry.[17] This was performed to ensure ratings were based on set criteria and to improve reliability. The assessments were originally carried out separately to ensure objectivity. When rating differences were larger than 1 or where one rating was ‘poor’ and the other ‘satisfactory’, a discussion took place over the reasoning and an agreement was made on the score. Agreement was reached on the ranking of studies with final total scores being either equal or within 2 points of each other. The final ranking scores can be seen in appendix 1.

Data Extraction

Outcome measures were extracted in raw data including sedation rates along with cost findings and image assessment, where applicable. Where figures were given for sedation and GA separately, these are combined in the analysis. The rationale for this combination is that the overall aim of the distraction technique should be to reduce any form of chemically induced compliance.

Data Analysis

A best evidence synthesis was completed based on Ryan.[19] A comparison of pre and post intervention sedation rates was compiled in bar chart format (if applicable). A table of intervention type was also compiled. Where image quality and cost were included in the studies, these data were also extracted.

Results

Four of the five papers employed protocols based on Raschle et al[20], in terms of their approach to sensitising children to the MRI machine prior to the scan taking place. An overview of the protocols is given in table 3. Although a number of different approaches to distraction have been identified it is clear that common themes appear in the papers identified.

Study Design

There was significant heterogeneity throughout the data collected from the studies[21,22,23,24,25] and this can be seen in table 3. One study gave an intervention to all participants[21] and compared two different imaging sites (these were termed 'expensive' and 'inexpensive' mock scanners). Three studies employed a pre/post intervention design through collecting retrospective data before intervention and then comparing this with the intervention period.[23,24,25] One study employed a randomised controlled trial.[22]

Length and Type of Intervention

Four of the five studies[21,22,23,24] included were based on the Raschle et al[20] protocol. This involved using play to prepare the child for undergoing the procedure (see table 3). For example, these techniques include 'statue game', scanning toys in toy sized MRI scanners, and role play. These interventions were typically undertaken by a play therapist[22,23], by radiography staff, or researchers who have undertaken training.[21,24]

Durand et al[25] differed significantly with the other studies in that the intervention consisted of a referral to a certified child-life specialist (CCLS) only (i.e. play therapy was not used). These professionals are certified by the Child Life Certification Commission, which regulates the profession. The children were referred to the professional for two weeks prior to their scan; however, no data were given as to how long the intervention lasted. The CCLS did not use any of the equipment that is being used in the other studies (such as mock scanner, role play, etc.). The CCLS used predominately guided imagery to help the child cope with the experience.

Effectiveness of Techniques Employed

The overall effectiveness of the techniques employed in all studies was measured via rates of sedation (see fig. 2). Some studies aggregated this and others separated out these outcomes. Data were extracted where participants have been in the 4-10 age range. Findings for the success rates of the interventions can be seen in figure 2.

Costs of Setting up Service

Cost was not primarily assessed within all of the papers. Runge et al[23] and Cavarocchi et al[23] used the 'Kitten Scanner and Ambient Environment®' (Philips; Eindhoven, Netherlands). As a proprietary method, this may be seen as incurring a cost given the implementation of such a system which was estimated at 181,916 EUR[24]. Whilst this cost included staff training and no breakdown was given, it is probable that a significant capital outlay is required given the costs of other proprietary mock scanners.[26] Barnea-Goraly et al[21] utilised an 'inexpensive mock scanner' comparing both an expensive and inexpensive comparison (see fig. 3). Whilst no cost is given for the expensive option, the cost of inexpensive mock scanner is quoted at $80 plus the cost of an iPod® (Apple; Cupertino CA; USA). Durand et al[25] utilised a change in workflow sending all participants between the identified age ranges to a CCLS. This increased referrals from 47 per year to 236 per year. However, costing for the referrals, nor the cost of anaesthesia, is given. A proportion of those patients referred still required some form of sedation.

Image Quality and Scan Length

Runge et al[24], Bharti et al[22] and Cavarocchi et al[23] all developed scoring assessment for the quality of images included. Bharti et al[22] stated that, no images were repeated for poor image quality. Cavarochhi et al[23] rated image sequences as either sufficient or not sufficient and stated that all scans were of sufficient image quality. This implies a 100% success rate at gaining scans of a sufficient image quality. Runge et al[24] developed a scoring system for assessing whether images were deemed satisfactory or not was in place using a three point scale (Excellent/good, acceptable, and not acceptable). No images were deemed not acceptable (see fig. 4). There was a reduction in image quality in the intervention group but this was not statistically significant (p=0.37). The number of scans where no images were achieved was the same across the control and intervention group (n=1 in each arm). This indicates that there was no overall decrease in image quality across the study. These findings appear similar to Bharti et al[22] and Caraochhi et al.[23]

The studies included here conducted their interventions across a range of MRI examinations. Some included only head scans[21] and others the entire body.[22] This does not appear to have an influence of the efficacy of the distraction technique in reducing sedation rates, as four of the five studies had very similar sedation rates (see fig. 2).

Only Runge et al[24] gave any indication of the scan times. No significant differences were demonstrated between control and intervention groups (fig. 3).

Discussion

An issue with the papers included in this review is the significant heterogeneity in the methods employed. For example, Cavarocchi et al[23] used their intervention on those children who had been identified by the referring clinician as requiring an intervention (e.g. GA). In Barnea-Goraly et al[21] there was no comparison of a control or baseline group of children, but rather of 'expensive' distraction (defined as a large proprietary mock scanner simulator) and 'inexpensive' distraction with no statistically significant difference observed between the cohorts. Barnea-Goraly et al[21] also compared different sequences; a T1-weighted and diffusion-weighted imaging (DWI) sequences, with no significant difference found. Whilst one may assume that this was performed to compare different types of scan, no rationale is given.

Similarities across sedation rates following intervention occur with Cavarocchi et al[23], Barnea-Goraly et al[21] and Bharti et al[22] ranging between 19 – 21.6% across all studies. Bharti et al[22] is the only randomised control trial and shows comparable post intervention rates to other study designs. There is, however, a significant variation between the types of MRI scan performed. This is outlined in table 3. However, even with this heterogeneous data, it is clear that there is a drop in sedation rate and an increase in child compliance within the studies shown, for those interventions based on Raschle et al.[20]

Durand et al[25] is slightly more complex. In their analysis figures for the age range in our inclusion criteria are given for general anaesthetic only (see figure 2) not other forms of sedation. However, the results make for interesting reading as there is still a significant rate of anxiolytic use in the 5-18 age range in children undertaking the CCLS pathway (37/136 cases required diazepam use). This means that from our criteria (i.e. administration of any consciousness altering substance), there would still be significant use of sedation with this particular intervention, even though GA had been avoided.

Raschle et al[20] produced a paediatric neuro-imaging protocol incorporating previous distraction intervention research. All studies within this review complied with this intervention except Durand et al[25] which focussed on using a CCLS. Therefore, it could be argued that the techniques advocated within Raschle et al.[20] are effective and this borne out within the literature and within Durand et al.[25] The anaesthetic rate within Durand et al[25] was higher (46%) than within the other four studies based upon the Raschle et al[20] protocol (range 5-20% total sedation rate). Durand et al[25] also described a anxiolytic administration rate of 20% within the CCLS arm of their study, although no information is given with regards to the age group that this applies to. This rate arguably places this technique (i.e. not based on the Raschle et al[20] protocol) as being potentially less effective.

Adaptations of the Raschle et al[20] has shown consistent results in this review and variations of it can be found in previous studies showing post intervention sedation rates ranging from 0.6 to 30%[25,26,27,28] across a wider age range of 3 to 17 years. The lowest post intervention result was Pressdee et al.[27] This was carried out at a centre where anaesthetic support in MRI was not readily available to patients. This could have had a potentially positive influence on the results, as staff may have been dissuaded from asking for anaesthetic support due to its apparent scarcity. Munn et al[13] contained 5 case-control/cohort studies[26,31,32,33,34] and three RCT designs[35,36,37]. Tyc et al[36] used cognitive behaviour techniques and a mock scanner with children between 6 and 18 years and found no significant difference in sedation rates between those who received the intervention and those who didn't. However, the mean age of participants was 12.5 years which may have an effect upon their results. Smart[37] did notice an improvement using guided imagery and music at similar levels to previously cited research. However, this is not replicated within Durand et al[19].

Two studies within this review assessed brain scans specifically[21,23] and others incorporated them. This is possibly significant as MRI head scans are particularly susceptible to movement artefact.[38] There does not appear to be a noticeable difference in post-intervention sedation rates between the studies. There does not appear to be any correlation between the types of scans that have been undertaken and the sedation rates seen within the studies included. One may expect to see a change in compliance as the scans get longer[39] however, this does not appear to be the case. The types of patients scanned across all studies were out-patient department referrals and no studies included patients who were urgent referrals.

Durand et al[25] included scans of 60 minutes and less and perhaps as a result, success rates were substantially lower than others in this review. In comparison, Runge et al[25] gave results for scan times below 20 minutes, 20-30 minutes and above 30 minutes although a maximum time was not stated which is a limitation of the study.

An indication regarding deployment of play therapy may be to use paediatric play specialists or play therapists to train MRI radiographers in incorporating appropriate interventions, rather than a range of staff from other departments such as occupational therapists and play specialists which may not be available at all MRI sites that undertake paediatric MRI scans. This is also a skill which would be utilised day to day outside the intervention protocol. It was also found by applying a mandatory referral to a distraction therapy there was a possible decrease in caseload variability from 49% to 18% resulting in the potential for overall better allocation of resources.[25] Furthermore, previous papers have concluded that waiting times could decrease through implementing distraction[35] as much as from 50 to 23 days through implementing the Children Centred Care concept.[25] In addition, general costs have been reported to increase by multiples of 3.24 for patients needing sedation and 9.56 for those requiring anaesthetic, compared to those who don't adding further weight to the possible economic benefits of implementing appropriate distraction techniques.[40]

The initial cost to establish some of these interventions (in particular those using proprietary equipment) may appear high but the approach could be adapted in terms of type of mock scanner such as that in Barnea-Goraly et al.[21] For example, Theys et al[41] achieved comparable results without any mock scanner and using play alone. There was also a more stringent level of image acceptance than scans undertaken for clinical reasons would require.[41] In terms of mock scanner effectiveness, results were found to be comparable using the inexpensive mock scanner costing circa $80 compared to $224 000 (circa £176 000)[24] for a proprietary mock scanner.

Limitations

A large number of studies whose age range extended beyond the inclusion criteria being excluded from this review could be viewed as a limitation. However, this was carried out to ensure applicability of any recommendations. A separate study covering patients with conditions in the exclusion criteria may be necessary in the future, along with a study around adaptations to the protocol for in-patients. Randomised controlled trials are the preferred study design required for future research and larger patient groups would add further validity, with potential stratification across age ranges. However, one should note that although age is an important variable, it is used here as a proxy for development and the intervention should also be directed towards the child and not their age.[43]

The costs given in the papers were often incomplete and focused on only the purchase of equipment and not staffing. For example, Runge et al[24] did not include the cost of training the radiographers to undertake these interventions and Barnea-Goraly et al[21] did not highlight the costs of the play therapists. However, the interventions here are based on a similar protocol[20], therefore if an assumption is made that the costs for training were similar across the interventions then we can see that equipment costs can be substantially reduced through using non-proprietary equipment.[21,22]

The major limitation of the current literature, as stated previously, is the heterogeneity of the literature presented. However, despite this, the body of evidence does point towards play therapy and sensitisation of children to MRI does affect their ability to comply with these types of examinations. Further studies may also focus on any changes in false positive/negative rates within the methods, as this could indicate changes within diagnostic image quality.[44]

Conclusion

Despite methodological heterogeneity within the literature, there is a clear recurring theme that effective engagement with children prior to their scan (using play) reduces the need for sedation. The interventions within the review appear to be implementable, whilst certainly not homogenous. The effective use of play and the use of simulation prior to undergoing a scan appears to reduce the need for sedation within this age group. A large capital outlay may not be required for these techniques to be implemented, as inexpensive options appear to yield equally effective results.

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Figures

PRISMA 2009 Flow Diagram

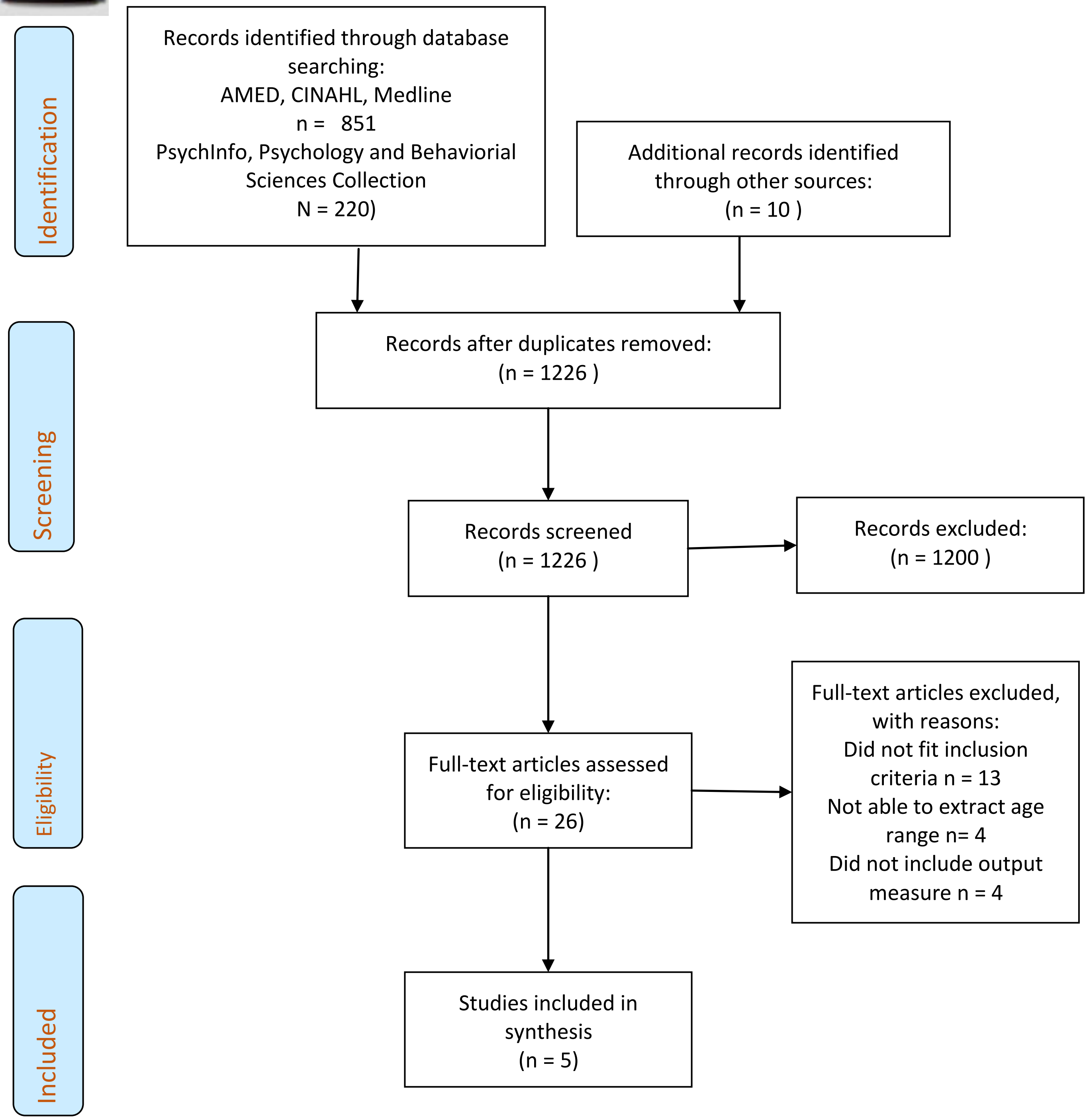

Fig1. PRISMA chart

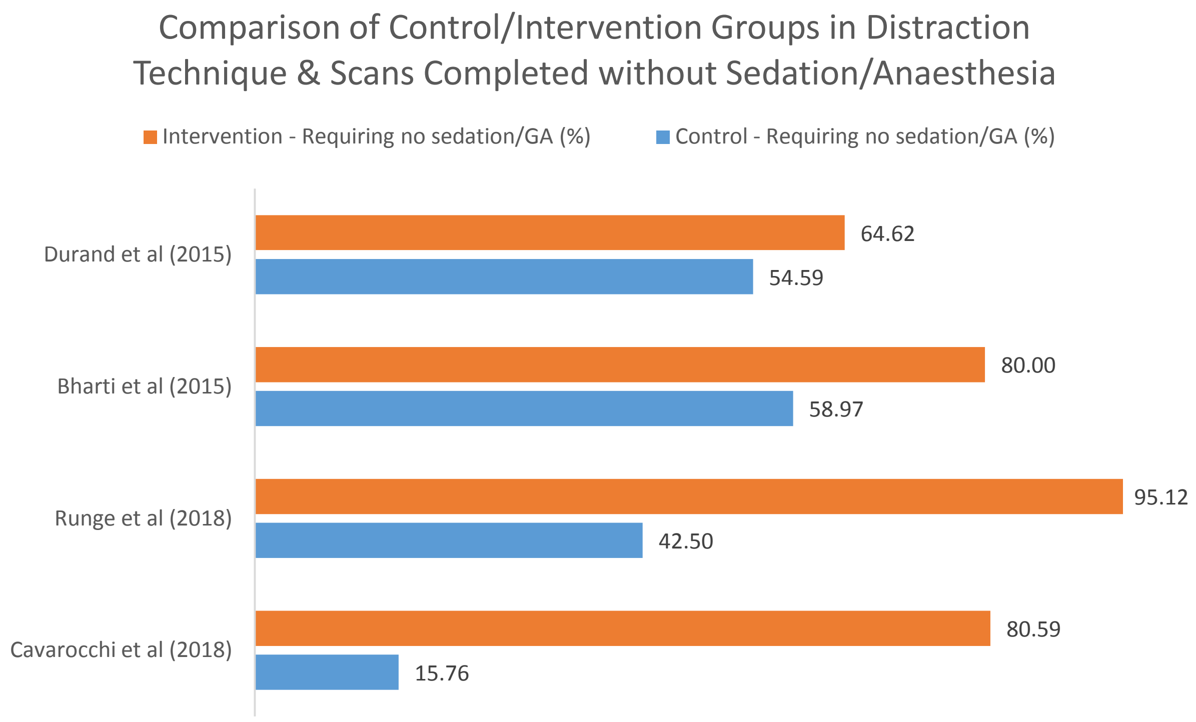

Fig 2 - Comparison of Control/Intervention Groups in Distraction Technique & Scans Completed without Sedation/Anaesthesia

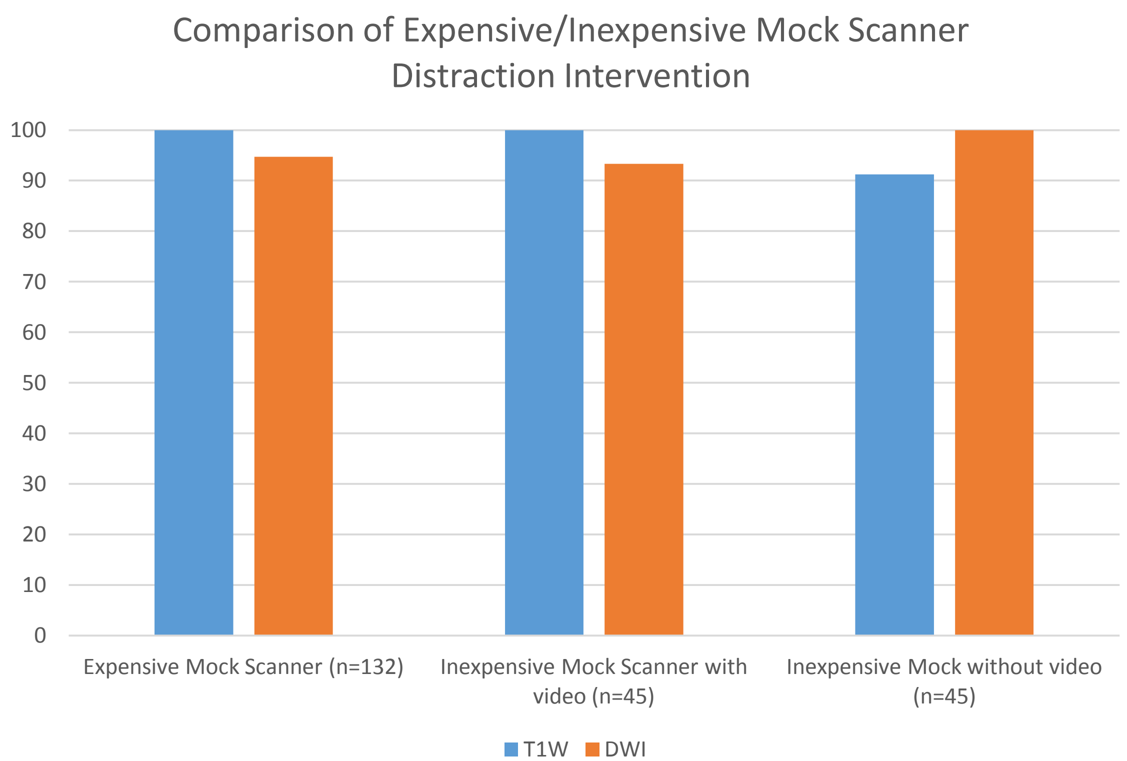

Fig.3 - Comparison of Expensive/Inexpensive Mock Scanner Distraction Intervention in Barnea-Goraly et al (2013)

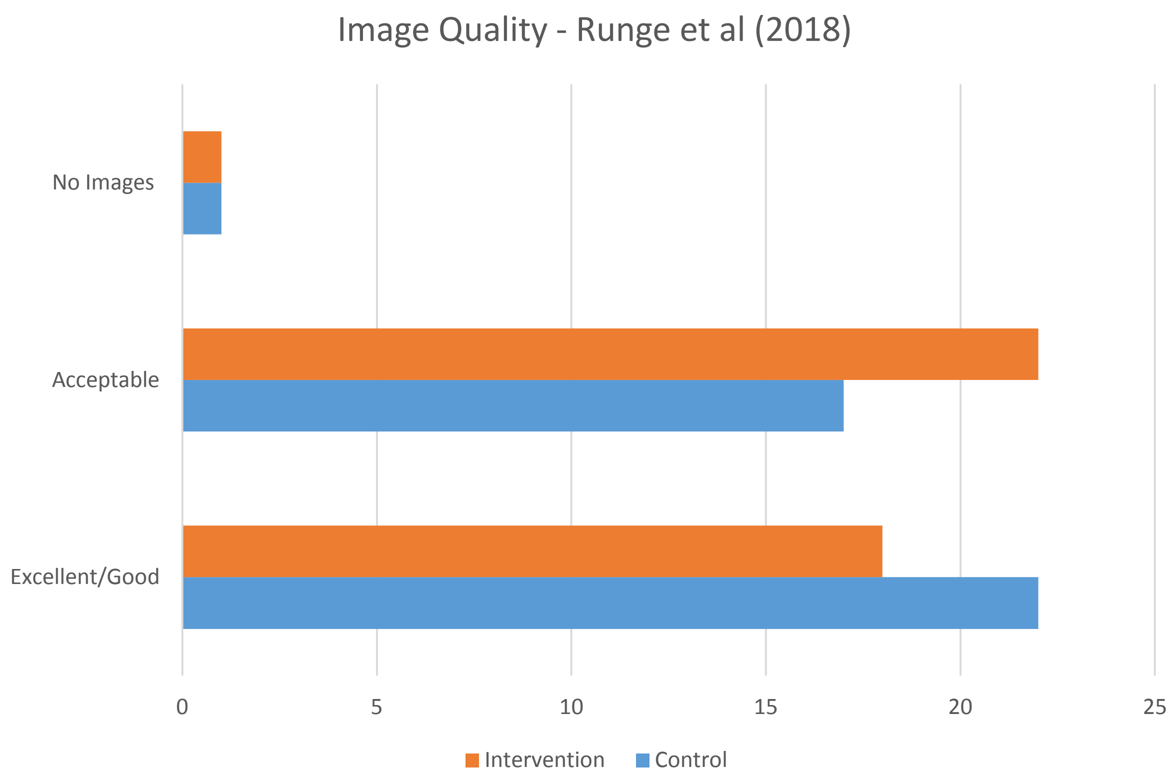

Fig 4. Image quality measures taken from Runge et al (2018)

Tables

Table 1: *A priori* inclusion and exclusion criteria

Inclusion	**Exclusion**
Years Jan 2011 – Dec 2018	Qualitative research (unless part of a paper containing the inclusion quantitative outputs).
4 to 10-year-old patients or within that age bracket undertaking an MRI scan.	Children with known mental disability (such as autism, ADHD), neurodevelopmental disorders, developing atypically, suffering from extreme claustrophobia, unable to communicate verbally.
Primary research only.	
Texts in English Language. All body parts.	
A measure output of percentage of patients requiring sedation/GA required after an intervention.	
All types of interventions in the time frame.	

Table 2: Boolean operators and keywords used for searching the following databases: CINAHL, Medline, AMED, PsychArticles, PsychInfo, Psychology and Behaviourial Sciences Collection, and ScienceDirect (2018 ONLY)

(“Paediatric” OR “Pediatric” OR “children”)
AND
(“MRI” OR “Magnetic Resonance Imaging”)
AND
(“anaesthesia” OR “anaesthetic” OR “anesthesia” OR “anesthetic” OR “sedation”)
AND
(“distraction techniques” OR “play”)

Table 3: Overview of papers included in the review

	Study Type		Participant Number in arms*	Intervention Overview	Length of intervention	Intervention During scan	Child Age	Intervention set-up cost (if given)	Body Parts Scanned
Cavarocchi et al (2018)	Control vs intervention	Pre/post intervention	C n=286 I n= 477	Kitten Scanner (Philips) used with a child life specialist including role play.	30-40 min per child	Child Friendly MRI Suite (Phillips)	4-9 year data extracted	Est. from Runge et al (2018) 181,916 EUR	Brain only
Runge et al (2018)	Control vs Intervention	Pre/post intervention	C n= 57 I n= 80	Kitten scanner (Philips) and specific application	15 min per child (not including the app part of the intervention)	Child Friendly MRI Suite (Phillips)	4-6 years	181,916 EUR	Head, neck, spine, extremities, pelvis abdomen
Barnea-Goraly et al (2015)	Expensive mock scanner vs Inexpensive mock scanner (both employ a Behaviour desensitization program)	Comparison of two scanning sites.	E n= 132 I n= 90	Expensive program: Full Size Mock Scanner Inexpensive Program: iPod enhanced toy tunnel, hat box, massage mat & 'Statue' game (play therapy)	30-60 min per child	None noted.	4-9.9 years	Expensive: not given (est. $224,000 from Cater et al (2010)) Inexpensive : $80 + iPod Touch	Head Only
Durand et al (2015)	Baseline vs Intervention	Retrospective comparison	C n=47 I n=234	Certified Child Life Specialist referral.	Not noted.	Guided imagery	5-10 data extracted	n/a	No information given.
Bharti et al (2015)	Control vs Intervention	Randomised Controlled Trial	C n= 62 I n= 72	Toy small Mock Scanner Model (not proprietary) and audio recordings (play therapy)	30-40min per child	none noted	4-10 years	n/a	All referrals excluding trauma.

*C=Control; I=Intervention; E = Expensive program; I= Inexpensive program.

Appendix

Table 1: Table showing total scores per independent review.

	RATER	OVERALL SCORE
RUNGE ET AL	RF	47
	GS	46
DURAND ET AL	RF	30
	GS	30
CARAROCCHI ET AL	RF	41
	GS	39
BAHARTI ET AL	FR	49
	GS	49
BARNEA-GORALY ET AL	RF	41
	GS	40